



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,666	02/11/2004	Tushar Patel	101896-0233	3475
21125 7590 07/02/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER PELLEGRINO, BRIAN E				
ART UNIT		PAPER NUMBER		
3738				
NOTIFICATION DATE		DELIVERY MODE		
07/02/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/776,666

Applicant(s)

PATEL ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13,15-26,28,29,31-44,46-54 and 86-93 is/are pending in the application.
- 4a) Of the above claim(s) 25,29,32,39-44,47 and 49-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,11,12,15-24,26,28,31,33,34,36,37,46,48 and 86-93 is/are rejected.
- 7) ☒ Claim(s) 9,10,13,35 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 86-90 are rejected under 35 U.S.C. 102(b) as being anticipated by Santangelo (5067477). Fig. 1 shows a guide device with first **14** and second **16** members slidably movable with respect to one another and adapted to be positioned on a spinal plate. It can be seen that there are a plurality of opposing tabs **24** that are substantially C-shaped and is adapted to match the contour of the perimeter of a spinal plate. The guide members also include first and second pathways in a direction perpendicular to the axis of the guide members since there is spacing that extends between the tabs from a proximal to distal end of the tabs and would allow a tool to be inserted there between. It can also be construed that there are cutout portions formed in the guide members that provide a holder for the tabs which would retain the plate but allows for visualization of the plate between the guide members.

Claims 91,93 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulrich (DE 4201043). Fig. 6 shows a guide device for use with a spinal fixation plate. The guide device includes first **22'** and second **22"** arms slidably movable with respect to one another. It can also be seen the arms each include a guide member **21** coupled to the distal end of the arms and have opposed cutout portions in the opposed sidewalls at the distal ends of the guide members. It can be construed since the arms and guide members are positioned adjacent one another the cutout portions, walls and pathways

can be interpreted to "oppose" one another. Fig. 5 shows that the cutout portions are adapted to provide visualization of the positioning device that is coupled to the spinal fixation plate.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. '599. Phillips is explained supra. However, Phillips does not explicitly disclose the adjustment mechanism comprises a spring-lock mechanism to move between different locked positions. Spring-lock mechanisms are well known in the art. It would have been obvious to one of ordinary skill in the art to substitute a spring-lock mechanism with the housing of Phillips such that it ensures that when the arm is positioned at the desired location the surgeon does not have to worry it will slip out and move during surgical use. Such a modification only involves routine skill in the art.

Claims 1,3-8,11,12,15-23,26,28,31,33,34,36,37,46,48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coates et al. (5423826) in view of Phillips et al. '599. Coates discloses (Fig. 17) a guide device for use with a spinal fixation plate with the device having two movable arms **151,152** and first and second guide members **157** coupled at the distal end of the arms. There is an elongate support member **155** coupled to a proximal end of the arms since they originate (see Fig. 17) where the elongate member is located and extend therefrom in a direction transverse to the arms

and is adapted to slidably mate with the arms. Additionally, the arms have a distal portion that is at an angle to the proximal portion (Figure 20). Each guide member (157) comprises a housing with opposed first and second pathways (Figure 16) where the housing or guide member contains a lumen sleeve (180) which has a rounded tip extends through the barrel into the rounded recess of the accompanying plate. Each pathway in the guide is in communication with each other via a cut out at a distal portion formed in the housing between the first and second pathways (Figure 16) where the cut out portion extends from the housing where the pathways (158) are in communication through the body of the guide. It can be seen there are opposed cutout portions between hooks **161** or tabs that are C-shaped and allow communication between the two pathways in the guide member and this space is adapted to seat a spinal plate. However, Coates et al. fail to disclose the elongate member is curved. Phillips et al. teach (Figs. 1,2) a surgical instrument with adjustable arms used with a curved elongate support member that are capable of being locked (abstract). Phillips et al. teaches that a curved support structure would allow deeper access to the surgical site, col. 4, lines 61-64. It would have been obvious to one of ordinary skill in the art to substitute the curved support member and its attachment mechanisms for securing to arms as taught by Phillips et al. with the arms and guide members of Coates et al. such that it provides the surgeon with better or deeper access into the surgical site to implant the plate and could have the arcs of the plate match the elongate support.

Claims 1,3,15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. (7147599) in view of Sherman (4887596). Fig. 1 shows a guide

device with an elongate curved support member **12** that is capable of matching the contour of the spinal column. The guide device also includes first and second arms (**18,20**) each having a proximal end transversely coupled to the elongate support member and are slidably movable along the support member to allow a distance between the first and second arms to be adjusted. It can also be seen at the distal end of each arm is a guide member with a pathway formed therein. Regarding claims 16,17, the arms are mated with a proximal portion of the guide members and Fig. 5 shows that the distal portion of each arm can extend at an angle with respect to the proximal portion. With respect to claims 18,19, the guide members have a shape that is adapted to match the contour of a spinal fixation plate and have opposed tabs extending distally into the pathway and adapted to engage the spinal plate. Regarding claim 22, Fig. 2 shows the first arm can be fixedly mated and the second arm is slidably mated to the support member. With respect to claim 23, the guide device has an adjustment mechanism formed as part of housing **22** at the proximal end of the second arm to allow movement along the support member. However, Phillips fails to disclose a second pathway at the distal end of the guide member. Sherman shows a guide with first and second pathways in the block portion (**21**) placed in the guide end to secure rod better. It would have been obvious to one of ordinary skill in the art to use a second pathway to secure a rod using multiple set screws as taught by Sherman with the guide member of Phillips such that it provides a stronger fastening when an object is placed in the hooked guide. Phillips only shows a single fastening element to secure an object in the guide space. Thus, it is an obvious expedient to add a second using two pathways as

taught by Sherman. The intended use carries no weight in the absence of any distinguishing structure.

Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich DE (4201043). Ulrich is explained supra. However, Ulrich does not disclose having the cutout portions extend from the proximal end to a position near the distal end. It would have been obvious to one of ordinary skill in the art to modify the length and location of the cutout in the guide of Ulrich since such a modification only involves routine skill in the art and would not effect the function of the apparatus.

Response to Arguments

Applicant's arguments filed 2/25/08 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., opposed cut out portions means multiple or two cut-outs on the same guide member) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The Examiner interpreted "opposed cut-out portions" to be with respect to one another, that is the guide members, not that there are multiple cut-outs on a single guide since that is not clear from the language of the claim.

In response to applicant's argument that the Santangelo reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the apparatus includes arms) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). First it should be noted claim 86 only recites "guide members" to include the tabs, not any arms, so Applicant's representative is mistaken that the claim recites arms to include tabs. Second the claim does not establish any location as to where these tabs have to be other than extending distally from the guide members of which they do since a pin extends out to place the tabs out away from the guide members. Third, since each of the tabs are spaced from one another along the guide members and have opposing tabs on each of the guide members it can be seen that a channel or pathway is established between the spaces to enable a tool to be inserted in a lateral fashion through each of the spaces between every set of tabs.

Regarding the Coates and Phillips rejection, Applicant argues that the arms' proximal ends are not coupled with the elongate support. However, the Applicant's representative is mistaken as clearly seen in Fig. 17 where the arms begin from a central part of the tool to split and form separate lengths. Thus, the elongate support is coupled to the "arms" at their proximal ends. Second Applicant argues that the combination would not have an advantage. However, the Examiner disagrees since the use of the curved elongated support having an arc can match the arc of the spinal plate

and thus the adjustment of the arms along the elongate support can match up with that of the plate with accuracy. Additionally, the Examiner's modification was to substitute the mechanism of using the arcuate support of Phillips with the system of Coates. A substitution of adjustment or locking mechanisms is well within ordinary skill in the art and would only involve routine expertise.

Allowable Subject Matter

Claims 9,10,13,35,38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3738

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738

